

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Verrier *et al.*

Appl. No.: *To Be Assigned (Div. of Appl.
No. 09/769,439; Filed: January 26, 2001)*

Filed: Herewith (January 23, 2004)

For: **Kit for Transvenously Accessing
the Pericardial Space Via the Right
Atrium**

Confirmation No.: *To Be Assigned*

Art Unit: *To Be Assigned*

Examiner: *To Be Assigned*

Atty. Docket: 1565.0020003/MBR/GSB

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$_____ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign

application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).

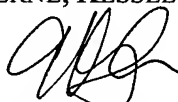
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. Copies of the documents are submitted herewith.
- ☒ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 09/769,439, filed January 26, 2001, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO 1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



George S. Bardmesser
Attorney for Applicants
Registration No. 44,020

Date: January 23, 2004

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT				ATTY. DOCKET NO. 1565.0020003/MBR/GSB		APPLICATION NO. To Be Assigned	
				FIRST NAMED INVENTOR Richard L. VERRIER			
				FILING DATE Herewith (January 23, 2004)		ART UNIT To Be Assigned	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	6,179,816	01/2001	Mottola <i>et al.</i>	604	264	
	AB1	6,162,195	12/2000	Igo <i>et al.</i>	604	164	
	AC1	5,968,010	10/1999	Waxman <i>et al.</i>	604	49	
	AD1	5,941,869	08/1999	Patterson <i>et al.</i>	604	508	
	AE1	5,725,512	03/1998	Swartz <i>et al.</i>	604	280	
	AF1	5,722,972	03/1998	Power <i>et al.</i>	606	7	
	AG1	5,713,849	02/1998	Bosma <i>et al.</i>	604	28	
	AH1	5,569,197	10/1996	Helmus <i>et al.</i>	604	96	
	AI1	5,554,114	09/1996	Wallace <i>et al.</i>	604	53	
	AJ1	5,476,450	12/1995	Ruggio	604	93	
	AK1	5,354,279	10/1994	Hofling	604	164	
FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 98/48881	11/1998	PCT			Yes No
	AM1						Yes No
	AN1						Yes No
	AO1						Yes No
	AP1						Yes No
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
	AR	1	Avitall, B. <i>et al.</i> , "A New Technique For AV Nodal Modification Using Pernodal Injection Of A Sclerosing Agent", <i>JACC</i> , Vol. 17, No. 2, February, 1991, pg. 174A. (Abstract only)				
	AS	1	Avitall, B. <i>et al.</i> , "Iontophoretic Transport of Procainamide and D-Sotalol Into Arrhythmogenic Myocardium: Efficacy in Ventricular Tachycardia Suppression", <i>JACC</i> , Vol. 17, No. 2, February, 1991, pg. 39A. (Abstract only)				
	AT	1	Avitall, B. <i>et al.</i> , "Iontophoretic Delivery of Dobutamine: An Effective Method To Increase Contractility of Non-Transmural Infarcts", <i>JACC</i> , Vol. 17, No. 2, February 1991, pg. 27A. (Abstract only)				
EXAMINER					DATE CONSIDERED		
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

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To Be Assigned**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,269,326	12/1993	Verrier	128	642	
	AB2	5,147,336	09/1992	Wendell <i>et al.</i>	604	283	
	AC2	5,137,510	08/1992	VanDeripe	604	28	
	AD2	5,092,848	03/1992	deCiutiis	604	170	
	AE2	5,033,477	07/1991	Chin <i>et al.</i>	128	785	
	AF2	4,998,975	03/1991	Cohen <i>et al.</i>	128	419D	
	AG2	4,991,603	02/1991	Cohen <i>et al.</i>	128	786	
	AH2	4,991,578	02/1991	Cohen	128	419D	
	AI2	4,961,731	10/1990	Bodicky <i>et al.</i>	604	264	
	AJ2	4,946,457	08/1990	Elliott	606	1	
	AK2	4,884,567	12/1989	Elliott <i>et al.</i>	128	303R	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Baim, Donald S. <i>et al.</i> , "Cardiac Catheterization, Angiography, and Intervention", Fifth Edition, <i>Williams and Wilkins Publishing</i> , U.S.A., 1996, pp. 809-813.
	AS	<u>2</u>	Brockenbrough <i>et al.</i> , "A New Technic for Left Ventricular Angiocardiology and Transseptal Left Heart Catheterization", <i>The American Journal of Cardiology</i> , December 1960, pp. 1062-1064.
	AT	<u>2</u>	Buselmeier, T.J. <i>et al.</i> , "Treatment of Intractable Uremic Pericardial Effusion: Avoidance of Pericardiectomy with Local Steroid Instillation", <i>Journal of the American Medical Association</i> , Vol. 240, No. 13, 1978, pp. 1358-1359.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA3	4,865,037	09/1989	Chin <i>et al.</i>	128	419D	
	AB3	4,769,016	09/1988	Labianca	604	280	
	AC3	4,765,341	08/1988	Mower <i>et al.</i>	128	785	
	AD3	4,717,387	01/1988	Inoue <i>et al.</i>	604	264	
	AE3	4,708,145	11/1987	Tacker, Jr. <i>et al.</i>	128	419D	
	AF3	4,699,147	10/1987	Chilson <i>et al.</i>	128	642	
	AG3	4,619,247	10/1986	Inoue <i>et al.</i>	128	6	
	AH3	4,567,900	02/1986	Moore	128	784	
	AI3	4,319,562	03/1982	Crosby	128	1R	
	AJ3	4,296,100	10/1981	Franco	424	108	
	AK3	4,292,976	10/1981	Banka	128	656	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2						Yes No
	AM2						Yes No
	AN2						Yes No
	AO2						Yes No
	AP2						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	DiCarlo, S.E. <i>et al.</i> , "Exercise Training Enhances Cardiac Afferent Inhibition of Baroreflex Function", <i>The American Physiological Society</i> , Order No. 0363-6135, 1990, pp. H212-H220.
	AS	<u>3</u>	Dorward, P.K. <i>et al.</i> , "Blockade of Cardiac Nerves By Intrapericardial Local Anesthetics In The Conscious Rabbit", <i>Aust. J. Exp. Biol. Med. Sci.</i> , Vol. 61 (Pt. 2), 1983, pp. 219-230.
	AT	<u>3</u>	Miyazaki T. <i>et al.</i> "Prostaglandins in the Pericardial Fluid Modulate Neural Regulation of Cardiac Electrophysiological Properties", <i>Circulation Research</i> , Vol. 66, No. 1, January 1990, pp. 163-175.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA4	4,256,115	03/1981	Bilitch	128	419P	
	AB4	4,181,123	01/1980	Crosby	128	6	
	AC4	4,173,981	11/1979	Mortensen	128	348	
	AD4	4,146,029	03/1979	Ellinwood, Jr.	128	260	
	AE4	4,003,379	01/1977	Ellinwood, Jr.	128	260	
	AF4	3,680,544	08/1972	Shinnick et al.	128	2R	
	AG4	3,630,207	12/1971	Kahn et al.	128	350R	
	AH4						
	AI4						
	AJ4						
	AK4						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL4						Yes No
	AM4						Yes No
	AN4						Yes No
	AO4						Yes No
	AP4						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Miyazaki, T. <i>et al.</i> , "Presynaptic Modulation of Efferent Sympathetic and Vagal Neurotransmission in the Canine Heart by Hypoxia, High K ⁺ , Low pH, and Adenosine", <i>Circulation Research</i> , Vol. 66, No. 2, February, 1990, pp. 289-301.
	AS	<u>4</u>	Uchida <i>et al.</i> , "Angiogenic Therapy of Acute Myocardial Infarction by Intrapericardial Injection of Basic Fibroblast Growth Factor and Heparin Sulfate: an Experimental Study", <i>American Heart Journal</i> , Vol. 130, No. 6, December, 1995, Pages 1182-1188.
	AT	<u>4</u>	Verrier, R. L., <i>et al.</i> , "Protective Zone and The Determination of Vulnerability to Ventricular Fibrillation", <i>The American Physiology Society</i> , 1978, Order No. 0363-6135/78/0000-0000, pp. H592-H596.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA5						
	AB5						
	AC5						
	AD5						
	AE5						
	AF5						
	AG5						
	AH5						
	AI5						
	AJ5						
	AK5						

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	AL5						Yes No
	AM5						Yes No
	AN5						Yes No
	AO5						Yes No
	AP5						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>5</u>	Verrier, R.L. <i>et al.</i> , "Prevention of Ventricular Fibrillation by Use of Low-Intensity Electrical Stimuli", Reprinted from <i>The Annals of the New York Academy of Sciences</i> , 1982, pp. 355-370.
	AS	<u>5</u>	Verrier, R.L. <i>et al.</i> , "Transatrial Access to the Normal Pericardial Space-A Novel Approach for Diagnostic Sampling, Pericardiocentesis, and Therapeutic Interventions", <i>Circulation: Journal of American Heart Association</i> , on or about December 8, 1998 (based on information presently available), pp. 2331-2333.
	AT	<u>5</u>	Welt <i>et al.</i> , "Second International Symposium on Cardiovascular Drug Delivery", <i>Circulation, American Heart Association</i> , Vol. 95, No. 4, February 18, 1997, pp. 773-776.

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA6						
	AB6						
	AC6						
	AD6						
	AE6						
	AF6						
	AG6						
	AH6						
	AI6						
	AJ6						
	AK6						

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	AL6						Yes No
	AM6						Yes No
	AN6						Yes No
	AO6						Yes No
	AP6						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	International Search Report from PCT Appl. No. PCT/US00/07444, 5 pages, mailed July 12, 2000.
	AS	<u>6</u>	
	AT	<u>6</u>	

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